



# HOME SCREEN

SELECTOR OF DRUGS

301

302

USE SAVED FILTERS

303

REVIEW SAVED PROFILE

304

INVOKE PROPORTIONAL ENGINE SETUP

SEARCH BY DRUG: ☒ INGREDIENT ☐ NAME

SEARCH BY CATEGORY:

SELECT A SAVED SEARCH CRITERIA AND OPTIONS TO RUN, OR SELECT NEW.

SEARCH CRITERIA:

PROFILER

SCREENS DISPLAYING DESCRIPTIVE STATISTICS FOR A SET OF CASES. REACTIONS, DRUGS, AGE, SEX, ETC. PLUS USER-DEFINED DIMENSIONS ARE SHOWN. ABILITY TO CREATE 2-D TABLES FOR ANY DIMENSION PAIR, AS WELL AS ABILITY TO REPORT AND CHART RESULTS.

PROPORTIONAL

COMPUTE THE RELATIVE RATIO, PROPORTIONAL REPORTING RATE, EBM, IC AND ODDS RATIO TO ASSESS THE DEVIATION FROM EXPECTED RESULTS IN A TARGET CASE SET. INCLUDED IN THE ANALYSIS ARE THE CHI-SQUARE AND CONFIDENCE LEVELS. SELECT STATISTIC AND REACTION LEVEL TO DISPLAY DYNAMICALLY. DEFINE VISUAL HIGHLIGHTING OPTIONS TO HELP IDENTIFY SIGNIFICANT RESULTS.

FIG.3

BEST AVAILABLE COPY

# FILTER SCREEN

SEARCH CRITERIA DETAILS	
• SUMMARY	SEARCH CRITERIA NAME: ALENDRONATE0396 (DRUG LEGEND: A=ALL, S=SUSPECT, I=INGREDIENT, N=DRUG NAME)
401 ~ DRUGS (DETAILS)	VALUE
400 ~ REACTIONS (DETAILS)	INCLUDED INGREDIENTS
402 ~ DEMOGRAPHICS	ALENDRONATE SODIUM (A)
403 ~ REPORT DATES	DRUG BOOLEAN [ (ALENDRONATE SODIUM) ] [CONCOMITANT OFF]
404 ~ EVENT DATES	ALL [INCLUDED]
OUTCOMES	ALL
REPORT SOURCES	FROM: FEB 1, 1969 TO: MAR 6, 1996
REPORT TYPES	ALL
CASE SOURCES	CONGENITAL ANOMALY; DEATH; DISABILITY
EXCLUDED CASES	ALL
EXCLUDED DUPLICATE CASES	ALL
NOTES	CASE SOURCES
	EXCLUDED CASES
	EXCLUDED DUPLICATE CASES

FIG.4

503  
(THERAPEUTIC  
CATEGORY)

500  
(GENERIC, OR  
'INGREDIENT')

501  
(TRADE NAME)

QUERY SCREEN

SEARCH BY DRUG: ☒ INGREDIENT ☐ NAME

SEARCH BY CATEGORY:  ACE INHIBITORS (4)

4 TRADE(S) MATCHED

INGREDIENTS (ALL, SUSPECT)	NAMES (SHOW ALL NAMES)
ENALAPRIL MALEATE (1,0)  SHOW SOURCE...	<input type="checkbox"/> ENALAPRIL MALEATE TABLETS (1,0)
LISINAPRIL (13,8)  SHOW SOURCE...	<input type="checkbox"/> LISINAPRIL TABLETS (12,8) <input type="checkbox"/> PRINIVIL TABLETS (1,0)
HYDROCHLOROTHIAZIDE, TELMISARTAN (0,0)  SHOW SOURCE...	<input type="checkbox"/> MICARDIS HCT TABLETS (0,0)

TO VIEW DRUG LIST AND  
DEFINE LOGICAL RULES,  
CLICK "DETAILED SETUP".

NO. OF INGREDIENTS SELECTED

NO. OF DRUGS SELECTED

REVIEW SELECTION AND SET  
DETAILED OPTIONS

FIG.5

DATA PEDIGREE SCREEN							
600	601	602	603	604	605	606	607
MAPTO	VERBATIM	SOURCE	INCIDENTS	CASE COUNTS	PROCESSING	CROSS REFERENCE	FIRST/LAST
PROZAC	PROZAC	SRS	47953	47953	A	ORANGE BOOK	4/27/69-12/2/97
PROZAC	PROZAC	AERS	3309	3309	A	ORANGE BOOK	11/1/69-6/29/99
PROZAC	PROZAC (FLUOX)	AERS	2	2	M	NDCD	2/27/69-2/2/97
FLUOXETINE	FLUOXETINE HCL	AERS	122	122	M	ORANGE BOOK	6/27/69-1/2/97
ETC...							

FIG.6

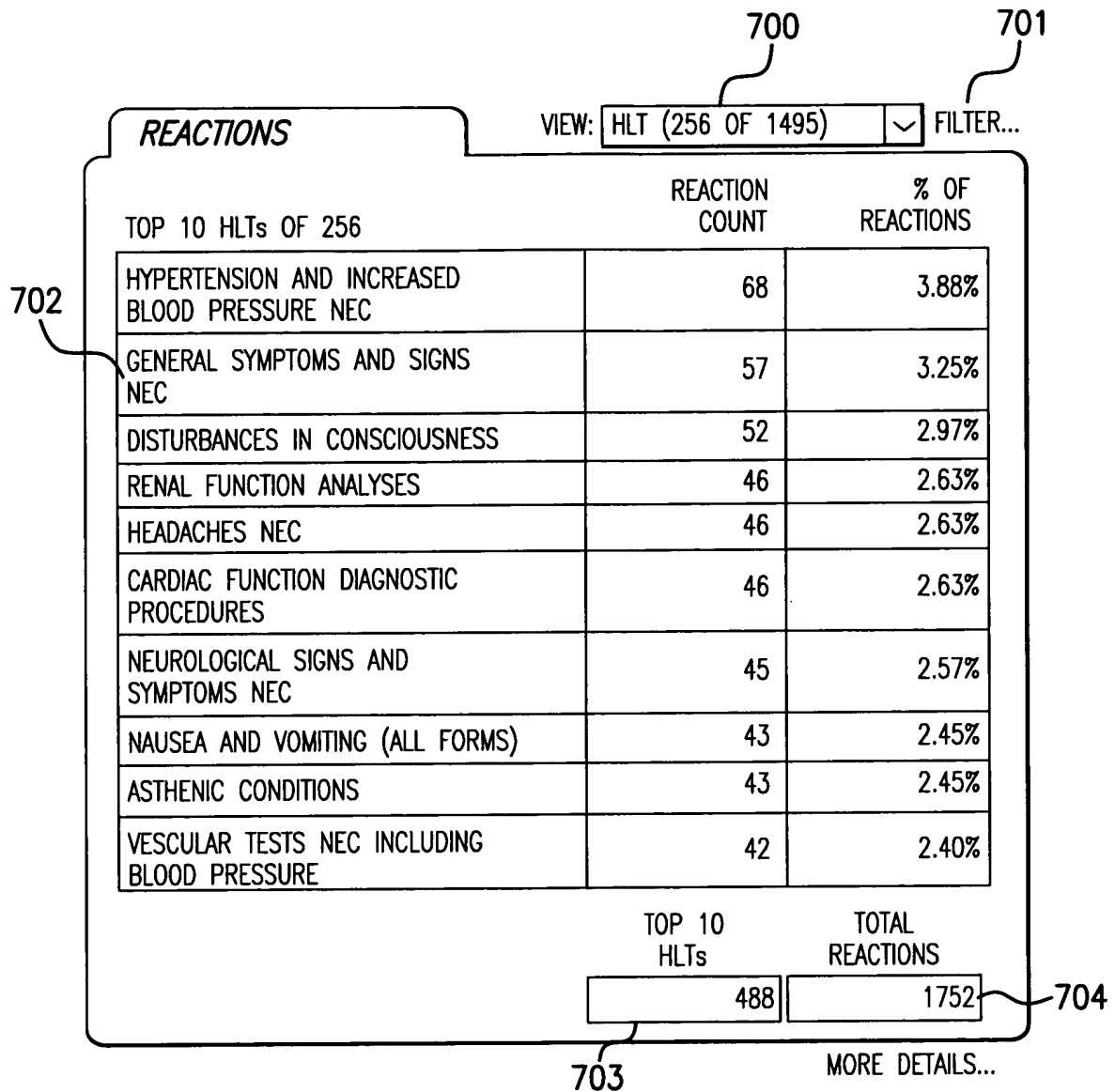


FIG. 7

800

801

802

CONCOMITANT DRUGS

FILTER...

TOP 10 DRUGS	SUSPECT		NON-SUSPECT		TOTAL	%
	S	NS	S	NS		
HYDROCHLOROTHIAZIDE	9	36	0	0	45	10.79%
ASPIRIN	2	38	0	5	45	10.79%
FUROSEMIDE	2	32	0	1	35	8.39%
DIGOXIN	0	30	0	0	30	7.19%
AMLODIPINE BESYLATE	0	24	4	0	28	6.71%
ENALAPRIL MALEATE	4	15	0	5	24	5.76%
VERAPAMIL HYDROCHLORIDE	11	10	0	2	23	5.52%
ESTROGENS, CONJUGATED	0	23	0	0	23	5.52%
METOPROLOL SUCCINATE	8	11	0	3	22	5.28%
METOPROLOL TARTRATE	0	15	0	7	22	5.28%

SUSPECT	NON-SUSPECT	
TOTAL	TOTAL	TOTAL
172	1141	1313

MORE DETAILS...

FIG.8

REACTION FILTER SCREEN

SEARCH REACTION:

FIND NEXT

RESET

INVERT REACTIONS

COLLAPSE REACTION TREE

DETAILED SETUP

- ☒ REACTIONS
- ☐ [SOC] BLOOD AND LYMPHATIC SYSTEM DISORDERS

☒ [HLGT] ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION

☐ [HLGT] BLEEDING TENDENCIES AND PURPURAS (EXCL THROMBOCYTOPENIC)

☐ [HLT] BLEEDING TENDENCIES

☐ [PT] BLEEDING TENDENCY

☐ [PT] HAEMORRHAGIC DISEASE OF NEWBORN

☒ [PT] HAEMORRHAGIC DISORDER

☒ [HLT] PURPURAS (EXCL THROMBOCYTOPENIC)

☒ [HLGT] COAGULOPATHIES AND BLEEDING DIATHESES

☒ [HLGT] HAEMATOLOGICAL DISORDERS NEC

☒ [HLGT] HAEMATOPOIETIC NEOPLASMS (EXCL LEUKAEMIAS AND LYMPHOMAS)

☒ [HLGT] HAEMOGLOBINOPATHIES

☒ [HLGT] HAEMOLYSES AND RELATED CONDITIONS

☒ [HLGT] LEUKAEMIAS

☒ [HLGT] PLATELET DISORDERS

☒ [HLGT] RED BLOOD CELL DISORDERS

☒ [HLGT] SPLEEN, LYMPHATIC AND RETICULOENDOTHELIAL SYSTEM DISORDERS

☒ [HLGT] WHITE BLOOD CELL DISORDERS

☒ [SOC] CARDIAC DISORDERS

☒ [SOC] CONGENITAL, FAMILIAL AND GENETIC DISORDERS

FIG.12

## CORRELATION SCREEN

1305			1300		1301		1306		1304		1303	
KEY ◆	CATEGORY◆	TERM 1 ◆	TERM 2◆	CATEGORY◆	SCORE◆	CASE ▲ COUNTS	DF◆	CONFIDENCE LEVEL	RANK			
☐...CANDESARTAN CILEXETIL					0.7283	2557	12317364	99.99				
☐...SEX					0.7283	2557	12317364	99.99				
FEMALE	DRUGS	CANDESARTAN CILEXETIL	FEMALE	SEX	0.7283	2557	12317364	99.99	1			
MALE	DRUGS	CANDESARTAN CILEXETIL	MALE	SEX	0.6481	2025	9753656	99.98	14			
SEX NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	SEX NOT SPECIFIED	SEX	0.2222	238	1142103	99.96	234			
☐...DEMOGRAPHICS					0.7190	2492	12004129	99.99	...			
AGE 51 TO 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 51 TO 75 YEARS	DEMOGRAPHICS	0.7190	2492	12004129	99.99	2			
AGE OVER 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE OVER 75 YEARS	DEMOGRAPHICS	0.4591	1016	4891285	99.97	23			
AGE NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	AGE NOT SPECIFIED	DEMOGRAPHICS	0.3986	766	3686535	99.97	45			
AGE 31 TO 50 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 31 TO 50 YEARS	DEMOGRAPHICS	0.3243	507	2438414	99.97	67			

RED YELLOW ORANGE

**FIG. 13**



CORRELATION DETAILS  
ANALYZED DRUG: CANDESARTAN CILEXETIL  
CASES FOR TERM PAIR: RENAL FUNCTION ANALYSES [OTHER REACTION]/RENAL FAILURE AND IMPAIRMENT [OTHER REACTION]  
CASES 1 TO 18 OF 18 CASES

	1401	1402	1403	1404	1405	1406	1407	1408
	CASE ID	SEX	MANUFACTURER CONTROL CODE	FDA REPORT RECEIPT DATE	AGE	DRUGS	REACTIONS	SERIOUS
1	3263641	F	19990300088	1999- 06-17	74	ATACAND	BLOOD CREATININE INCREASED; DIALYSIS Nos; RENAL FAILURE AGGRAVATED	N
2	3198047	F	19990200143	1999- 03-12	57	ACURETIC, ATORVASTATIN, ATACAND, CEFIXIME, NITRO-DUR, TERBASMIN EXPECTORANTE	BLOOD CREATININE INCREASED; BLOOD UREA INCREASED; HYPOTENSION Nos; RENAL FAILURE ACUTE	Y
3	3171644	F	19981100002	1999- 01-17	69	XANAX, ACETYSALICYLIC ACID, WELLBUTRIN, ATACAND, ARTHROTEC, DIGOXIN, LEVAQUIN, CLARITIN, ANTIVERT, PYRIDIUM, ZOLOFT, DYAZIDE, VERAPAMIL- SLOW RELEASE, AMBIEN	ABDOMINAL PAIN Nos; BLOOD CREATININE INCREASED; BLOOD UREA INCREASED; CORONARY ARTERY DISEASE Nos; HAEMOPTYSIS; HEART RATE INCREASED; HYPERTENSION AGGRAVATED; RENAL FAILURE ACUTE	N

FIG.14

## CASE DETAILS SCREEN

1501	CASE ID:	3641306				
1502	SEX:	F				
1503	AGE:	14 YEARS 0 MONTHS				
	WEIGHT:	NONE.				
	DEATH DATE:	NONE.				
1504	REACTIONS:	AS REPORTED	ONSET DATE	PREFERRED TERM		
		NAIL DISCOLOURATION	---	NAIL DISCOLOURATION		
		TOOTH DISCOLOURATION	---	TOOTH DISCOLOURATION		
		TREMOR NEC	---	TREMOR		
1505	CONCOMITANT DRUGS:	AS REPORTED	NAME	DOSE	ROUTE	DRUG ROLE
		ATACAND	ATACAND	16 MG QD PO	ORAL	PRIMARY SUSPECT DRUG
		ATACAND	ATACAND	12 MG QD PO	ORAL	SECONDARY SUSPECT DRUG
1506	OUTCOME:	OTHER(OT)				
1509	EVENT DATE:	NONE.				
	SENDING MANUFACTURER	ASTRAZENECA PHARMACEUTICALS LP				
1507	MANUFACTURER CONTROL CODE:	20000900273				
1508	MANUFACTURER DATE:	12 SEP 2000				
1510	REPORT CODE:	PERIODIC				
1511	REPORT SOURCE:	HEALTH PROFESSIONAL				
1512	CASE SOURCE:					
1513	NARRATIVE:	NONE.				

FIG.15

## CORRELATOR DISPLAY SCREENS

### COLUMN DISPLAY

KEY ◆	CATEGORY ◆	TERM 1 ◆	TERM 2 ◆	CATEGORY ◆	SCORE ◆
☐...CANDESARTAN CILEXETIL					0.7283
☐...SEX					0.7283
FEMALE	DRUGS	CANDESARTAN CILEXETIL	FEMALE	SEX	0.7283
MALE	DRUGS	CANDESARTAN CILEXETIL	MALE	SEX	0.6461
SEX NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	SEX NOT SPECIFIED	SEX	0.2222
☐...DEMOGRAPHICS					0.7190
AGE 51 TO 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 51 TO 75 YEARS	DEMOGRAPHICS	0.7190
AGE OVER 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE OVER 75 YEARS	DEMOGRAPHICS	0.4591
AGE NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	AGE NOT SPECIFIED	DEMOGRAPHICS	0.3966
AGE 31 TO 50 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 31 TO 50 YEARS	DEMOGRAPHICS	0.3243
AGE 16 TO 30 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 16 TO 30 YEARS	DEMOGRAPHICS	0.0827
AGE UNDER 16 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE UNDER 16 YEARS	DEMOGRAPHICS	0.0352
☐...OUTCOMES					0.6639
☐...DRUGS					0.3824
☐...REACTIONS					0.2452
DIZZINESS	DRUGS	CANDESARTAN CILEXETIL	DIZZINESS 75 YEARS	REACTIONS	0.2452
NAUSEA	DRUGS	CANDESARTAN CILEXETIL	NAUSEA 75 YEARS	REACTIONS	0.2121
HYPERTENSION NOS	DRUGS	CANDESARTAN CILEXETIL	HYPERTENSION NOS	REACTIONS	0.2116

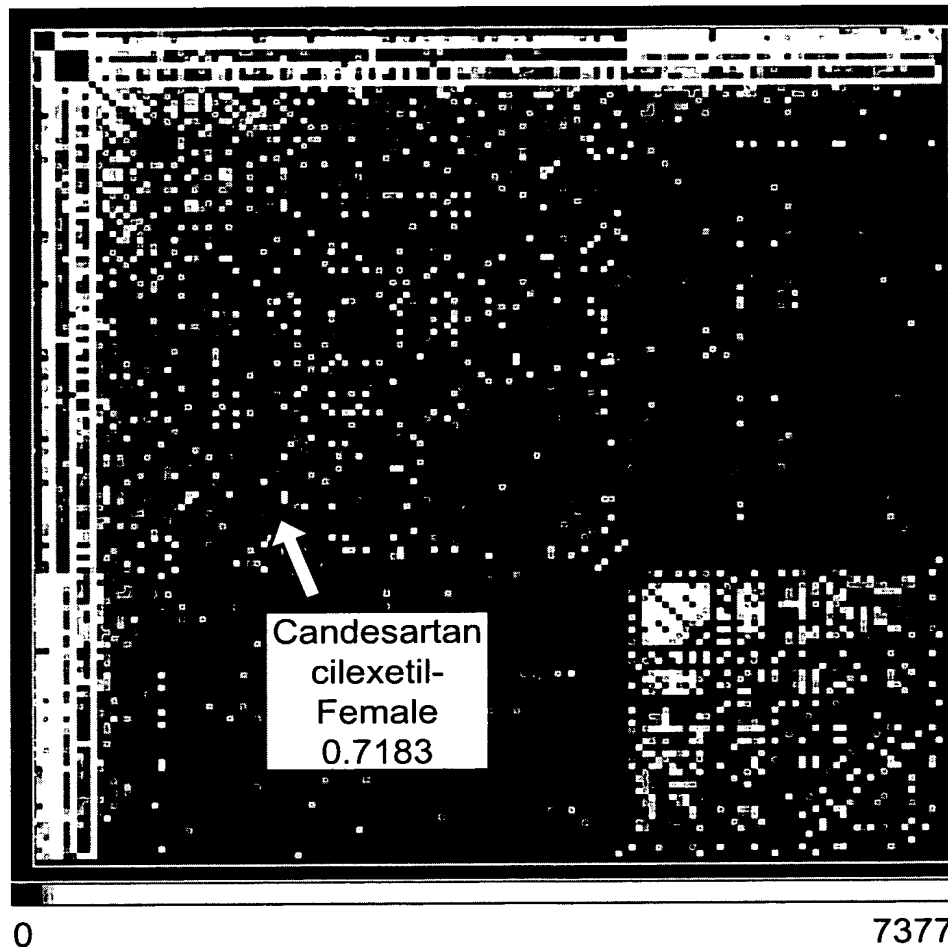
 RED
 YELLOW
 ORANGE
 PURPLE
 GREEN

FIG.16A

Best Available Copy

CORRELATOR DISPLAY SCREENS

"RADAR" DISPLAY (COLOR FOR SCORE)



Linear

FIG.16B

# PROPORTIONAL ANALYSIS RESULTS

## PROPORTIONAL ANALYSIS RESULTS

### PROPORTIONAL ANALYSIS

NAME: RMETHSUSP

DATE SAVED: 19 AUG 2005 19:18:36

DATA SET: FDA SRS/AERS COMBINED DATA-Q1  
2005

TOTAL CASE COUNT: 5478 (PROFILE CASE LIST) NOTES: NO NOTES TO DISPLAY

INGREDIENTS	TRADE NAME
METHADONE	
METHADONE HYDROCHLORIDE	

PRIMARY DIMENSION: REACTION VIEW: SOC		EXPAND TO VIEW		SECONDARY DIMENSION: NONE VIEW: NONE					
SOC HLGT HLT PT	REACTION	OBSERVED COUNT	PRR- EXPECTED COUNT	PROPORTIONAL REPORT RATIO (PRR)		PRR- CHI-SQUARE	PRR- CONFIDENCE LEVEL		
				SOC	HLGT	HLT	PT		
[SOC]1	BLOOD AND LYMPHATIC SYSTEM DISORDERS	89	343.66	0.26	1.73	32.34	44.18	188.7	9
[SOC]2	CARDIAC DISORDERS	916	537.25	1.70	3.87	27.67	86.25	267.0	9
[SOC]3	CONGENITAL, FAMILIAL AND GENETIC DISORDERS	161	49.59	3.25	6.64	10.98	301.87	250.3	9
[SOC]4	EAR AND LABYRINTH DISORDERS	12	60.27	0.20	0.23	0.60	6.04	38.7	9
[SOC]5	ENDOCRINE DISORDERS	17	33.03	0.51	1.61	5.66	301.87	7.8	9
[SOC]6	EYE DISORDERS	72	256.35	0.28	2.25	3.17	19.48	132.6	9
[SOC]7	GASTROINTESTINAL DISORDERS	391	1108.19	0.35	1.46	17.76	60.37	464.1	9

>3  
 2  
 3  
 .5  
 .333  
 .8  
 1.25

FIG.17

**PROPORTIONAL DISPLAY SCREEN: LINE**

1901	1900	1902	1903	1904
DRUGS	REACTIONS	EVENTS	RR- EXPECTED COUNT	RELATIVE RATIO (RR)
		59091	0.00	45.41
		59091	0.00	45.41
ABACAVIR SULFATE	BLOOD AND LYMPHATIC SYSTEM DISORDERS	11	18.14	0.61
ABCIKIMAB	BLOOD AND LYMPHATIC SYSTEM DISORDERS	380	44.28	8.58
ACARBOSE	BLOOD AND LYMPHATIC SYSTEM DISORDERS	29	9.91	2.93
ACEBUTOLOL HYDROCHLORIDE	BLOOD AND LYMPHATIC SYSTEM DISORDERS	12	10.75	1.12

>3  
 3  
 .8  
 1.25

**FIG.19**

2000

2001

2002

2003

2004

2005

2006

FIG. 20A-1

SOC HLGT HLT PT	REACTIONS	CLINICAL TRIAL REACTION	POST MARKET REACTION	REACTION COUNT DIFF (B-A)	REACTION COUNT RATIO (B/A)	% OF REACTIONS FROM A	% OF REACTIONS FROM B	% OF REACTIONS DIFF (B-A)	% OF REACTIONS RATIO (B/A)
◀[PT] 8.5.9	PAIN AND DISCOMFORT NEC	0	733	733	0	0.00	5.81	5.81	0.00
[PT] 8.5.9.10	PAIN NOS	0	529	529	0	0.00	4.19	4.19	0.00
[PT] 8.5.9.4	CHEST PAIN	0	204	204	0	0.00	1.62	1.62	0.00
◀[PT] 7.12.5	GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	660	719	39	1	6.60	5.69	-0.91	0.86
[PT] 7.12.5.1	ABDOMINAL PAIN NOS	660	719	718	1	6.60	5.69	-0.91	0.86
◀[PT] 15.1.2	BONE RELATED SIGNS AND SYMPTOMS	0	718	718	0	0.00	5.69	5.69	0.00
[PT] 15.1.2.1	BONE PAIN	0	718	718	0	0.00	5.69	5.69	0.00
◀[PT] 15.5.2	MUSCLE PAINS	0	677	677	0	0.00	5.36	5.36	0.00

2  
3  
8  
1.25

# COMPARATOR AND PRE-POST DETAILS SCREEN

		2007				2008			
SOC HLGT HLT PT	REACTIONS	CLINICAL TRIAL REACTION	POST MARKET REACTION	REACTION COUNT DIFF (B-A)	REACTION COUNT RATIO (B/A)	% OF REACTIONS FROM A	% OF REACTIONS FROM B	% OF REACTIONS DIFF (B-A)	% OF REACTIONS RATIO (B/A)
◀[HIT] 7.12.7	NAUSEA AND VOMITING SYMPTOMS	710	562	-148	1	7.10	4.45	-2.65	0.63
[PT] 7.12.7.2	NAUSEA	360	406	46	1	3.60	3.22	-0.38	0.89
[PT] 7.12.7.6	VOMITING NOS	100	156	56	2	1.00	1.24	0.24	1.24
[PT] 7.12.7.4	REGURGITATION OF FOOD	250	0	-250	0	2.50	0.00	-2.50	0.00
◀[HIT] 7.12.4	FLATULENCE, BLOATING AND DISTENSION	360	509	149	1	3.60	4.03	0.43	1.12
◀[HIT] 7.12.2	DYSEPTIC SIGNS AND SYMPTOMS	360	486	126	1	3.60	3.85	0.25	1.07
◀[HIT] 7.11.1	DIARRHOEA (EXCL INFECTIVE)	310	400	90	1	3.10	3.17	0.07	1.02
◀[HIT] 7.10.4	OESOPHAGITIS (EXCL INFECTIVE)	57	360	303	6	0.57	2.85	2.28	5.00

2 > 3 8 1.25

FIG. 20A-2



2009

REACTIONS◆	% OF REACTIONS FROM A ▼	% OF REACTIONS FROM B ◆
2010 HAEMOGLOBINOPATHIES	0.00	0.00
CHROMOSOMAL ABNORMALITIES AND ABNORMAL GENE CARRIERS	0.00	0.00
EAR AND LABYRINTHINE DISORDERS CONGENITAL	0.00	0.01
RESPIRATORY DISORDERS CONGENITAL	0.00	0.01
IMMUNODEFICIENCY SYNDROMES	0.00	0.00
CHLAMYDIAL INFECTIOUS DISORDERS	0.00	0.01
ECTOPARASITIC DISORDERS	0.00	0.00

2011

FIG.20B

2012

REACTIONS◆	% OF REACTIONS FROM A ▼	% OF REACTIONS FROM B ◆
BLEEDING TENDENCIES AND PURPURAS (EXCL THROMBOCYTOPENIC)	0.01	0.00
2013 HAEMOGLOBINOPATHIES	0.00	0.00
CHROMOSOMAL ABNORMALITIES AND ABNORMAL GENE CARRIERS	0.00	0.00
EYE DISORDERS CONGENITAL	0.02	0.00
IMMUNE SYSTEM DISORDERS CONGENITAL	0.01	0.00
IMMUNODEFICIENCY SYNDROMES	0.00	0.00
ANCILLARY INFECTIOUS TOPICS	0.01	0.00

2014

FIG.20C

## CASE LIST SCREEN

2100	2101	2102	2103	2104	2105	2106	2107	
CASE ID	SEX	MANUFACTURER CONTROL CODE	FDA REPORT RECEIPT DATE	AGE	DRUGS	REACTIONS	SERIOUSNESS	REPORTING COUNTRY
3319323	M	105204	1999/08/05	28	INVIRASE, RITONAVIR, ZERIT, HMD, ZIDOVUDINE, Nelfinavir Mesylate, VIDEX, SULFAMETHOXAZOLE + TRIMETHOPRIM, ANTICOAGULANT, HMD	BLEEDING TENDENCY, COAGULATION FACTOR VIII LEVEL DECREASED, ECCHYMOSIS, HAEMARTHROSIS, HEADACHE, LIVER FUNCTION TEST ABNORMAL, PLATELET COUNT DECREASED, RED BLOOD CELL COUNT DECREASED, SUBDURAL HAEMATOMA, WHITEBLOOD CELL COUNT DECREASED	HOSPITALIZATION-INITIAL OR PROLONGED	
3457806	M	10221083	2000/02/14	-1	ZERIT, EPVIR, NORVIR, INVIRASE, CRIVAN, ANTIHEMOPHILIC FACTOR VIII (HUMAN)	BLEEDING TENDENCY, HAEMATOCRIT DECREASED, HAEMOGLOBIN DECREASED, HEPATIC FUNCTION ABNORMAL Nos, TRANSAMINASES INCREASED	HOSPITALIZATION-INITIAL OR PROLONGED	
3489636	M	233093	2000/04/18	35	INVIRASE, ZERIT, EPVIR, NORVIR	BLEEDING TENDENCY, HAEMATOCRIT DECREASED, HAEMORRHAGE Nos, ARTHROPATHY Nos, RED BLOOD CELL COUNT DECREASED, THROMBOCYTHAEMIA	OTHER	

FIG.21

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record.**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**